REMARKS

I. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg

Claims 1, 2, 4-7 and 13-21 stand rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Lundberg (U.S. Patent No. 6,132,770). Applicants respectfully traverse the rejection.

The Examiner is still mistaken in thinking that since the cited reference teaches that an effervescing tablet has a disintegrating time of about 55 seconds, that the aspects of the invention presently claimed are obvious.

As Applicants have stressed before, the time referred to in the cited art (i.e. effervescence time) was measured by putting ***a tablet*** in a basket of metal wiring and then immersing the basket ***in 300 ml of water*** *(Example 1) or* ***in 150 ml of water*** *(Examples 3, 4, 5 and 6).* The dissolution times disclosed in the cited art were therefore obtained under vastly different conditions than Applicants' recited buccal dissolution times, measured as the time for healthy adults to complete disintegration by buccal saliva.

Those skilled in the art already understand that while the orally disintegrable tablet of the present invention is capable of being dissolved with the patient's saliva without additional water, the effervescent tablet of the cited art must be dissolved or dispersed in large amount of water before administration. The two methods of disintegration are non-analogous.

Applicants previously submitted a Declaration which proved this point, the Shimizu Declaration. On page 5 of that Declaration, Applicants showed that test patients could not even keep effervescent tablets in their mouths long enough to achieve dissolution, as after three minutes, it was too uncomfortable for them to keep the tablets in their mouth. This is so because effervescent tablets are not designed to dissolve orally. They are not analogous art to the presently claimed preparations.

The Examiner's comments on page 6 of the Office Action give two reasons for discounting the Shimizu Declaration. Applicants do not find her reasons to be logical. As to the first reason given, there is no need for a side-by-side comparison. By way of analogy, one may think of running two racecars side-by-side to see which is faster. But if one of the racecars is inoperable due to engine failure, there is no need for a race. Similarly, Applicants have already shown that effervescent tablets are inoperable for oral administration. There is no need

for a side-by-side test because Applicants have already proven that the art effervescent tablets are not even tolerable as oral treatments.

As to the second reason given, it is irrelevant that "the amount of CO_2 evolved in a patient's mouth is not what is being claimed". The tests in the Declaration showed that the effervescent tablets gave off so much CO_2 that patients would not be able to take them orally. Thinking back to the racecar analogy, the amount of CO_2 evolved is merely proof of the broken engine (inoperability). Since Applicants have recited buccal dissolution times in each of the independent claims, they believe that the evidence in the Shimizu Declaration is commensurate in scope with the pending claims.

So the Applicants have argued that the cited art is non-analogous, and reinforced that argument by presenting test data in the form of a Declaration. So far, four Declarations have been submitted in the pending application, to try to show the Examiner the differences between cited art and the presently claimed invention. Despite Applicants' every attempt to educate the Examiner, she continues to reject the present claims.

Since the Examiner has not been able to understand the differences between the dissolution of effervescent tablets in water and Applicants' claimed buccal dissolution in the form of presented arguments, supplemental supportive literature references and Declarations, Applicants now provide a conceptual idea for the Examiner to consider in order to illustrate the differences between the dissolution times of the presently claimed invention and dissolution times of the effervescing tablets, as in the cited art.

Television has been used to advertise the effervescent tablets known as ALKA-SELTZER. Perhaps the Examiner recalls the ads, wherein the phrase "plop, plop, fizz, fizz, oh what a relief it is" was sung. If the Examiner does not recall it, the advertisement can be heard by clicking on the word "jingle" found in the descriptive text at www.snopes.com/business/genius/alka-seltzer.asp. The "plop, plop" represented the sound of the tablet dropping into a glass of water, and the "fizz, fizz" represented the sound of effervescence begun as dissolution started taking place in the glass. This catchy tune educated the general public as to the administration method for taking effervescent tablets. Such a tablet does not go into the mouth for dissolution, but into a glass of water for dissolution.

Were the effervescent tablets efficiently or comfortably dissolvable in the mouth, "plop, plop, fizz, fizz" would be unnecessary. Dissolving an effervescent tablet in a large amount of

water is vastly different than dissolving an oral tablet in the mouth with saliva, where there is a paucity of water. That is why Applicants persist in arguing that the cited art is non-analogous.

Moreover, Applicants' previous Declarations have proven that human patients cannot tolerate "fizz, fizz" when it occurs in their mouths rather than in a glass.

The Examiner has pointed to the portions of the cited art which state that "[t]he novel tableted dosage form is intended for oral use" in col. 1, lines 13 and 14 and "[t]he tableted multiple unit effervescent dosage form is especially suitable for patients with swallowing disorders and in pediatrics" in col. 3, lines 53-55 to support her theory that the cited art teaches that effervescent tablets can be put directly into the mouth. Yet the Examiner has ignored the portion of the cited reference which describes effervescent tablet administration by that "[p]rior to being taken by the patient, an effervescent composition is dissolved and/or dispersed in for example an aqueous medium, such as drinking water." in col. 1, lines 63-66. When the reference is considered as a whole, it is clear that it does not stand for the proposition that an effervescent tablet can be put into the mouth for rapid dissolution.

The reference simply does not teach or suggest that effervescent tablets can be placed directly in the mouth.

Applicants find the Examiner's statement on page 6 that "nothing in Lundberg prevent (sic) a patient from administering the effervescent tablet my (sic) mouth, and nothing in Lundberg indicating that the effervescent tablet will not disintegrate in a patient (sic) mouth" to be absolutely lacking in merit.

Applicants have shown that it is common knowledge how effervescent tablets are administered (into a glass of water, *not* directly in the mouth) as illustrated by the ALKA-SELTZER example; and also provided experimental evidence to show that even if one defied conventional administration of an effervescent tablet and actually put it in the mouth, they could not retain it in the mouth long enough to be dissolved. The aspects of the invention as set forth in the present claims are thus non-obvious over the cited art.

Applicants wish to remind the Examiner that this application was filed in March of 2001, and has been the Examiner's responsibility the entire time. In approximately seven months, the application will be pending for five years, at which point it will qualify for "special" status according to MPEP 707.02.

Applicants do not believe that the aspects of their invention as set forth in independent claims 1 and 18-21 are rendered obvious by the cited art for the reasons provided above. Claims

2, 4-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious for the same reasons.

Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Lundberg.

II. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Lundberg in view of Watanabe *et al.*

Claims 1, 2, 4-7 and 13-21 have been rejected as being unpatentable over Lundberg, (U.S. Patent No. 6,132,770), in view of Watanabe *et al.*, (Biol. Pharm. Bull. 1995 article). Applicants respectfully traverse the rejection.

As an initial matter, Applicants note that the Examiner's comments on page 3 of the Office Action are contradictory. The Examiner first says that "Lundberg also teaches that the tablet having (sic) disintegrating time of about 55 seconds" near the top of the page, while at the bottom of the same page, the Examiner states "Lundberg is silent as to the teaching of the disintegration time in one minute or less".

Applicants have discussed Lundberg exhaustively in Sec. I above. Applicants hereby incorporate the arguments made in that section to this section.

The deficiencies of Lundberg are not cured by Watanabe *et al.* Note that Watanabe *et al.* discloses a compressed tablet comprising meclizine and L-HPC11 (or L-HPC21) in combination with crystalline cellulose. The hydroxypropoxyl content for LH-11 or LH-21 is **10.0-12.9%** (as shown in Appendix A; Shin-Etsu catalogue (Table 4) for L-HPC attached with the response as filed on January 15, 2002). There is no teaching or suggestion in Watanabe *et al.* of use of L-HPC having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group as is presently claimed in rejected independent claims 1 and 18-21.

Further, Watanabe *et al.* do not teach or suggest improving roughness or chalky taste, as recited in independent claim 21.

Applicants do not believe that the aspects of their invention as set forth in independent claims 1 and 18-21 are rendered obvious by the cited art for the reasons provided above. Claims 2, 4-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are also not rendered obvious by the combined teachings of the cited art for the same reasons.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Lundberg *et al.* in view of Watanabe *et al.*

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Makino *et al.* in view of Watanabe *et al.*

Claim 9 has been rejected as being unpatentable over Makino *et al.*, (U.S. Patent No. 5,501,861), in view of Watanabe *et al.*, (Biol. Pharm. Bull.). Applicants respectfully traverse the rejection.

Since neither Makino *et al.* nor Watanabe *et al.* disclose a solid preparation of the present invention including L-HPC having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group as set forth in pending claim 9, the combined teaching of the cited art does not render claim 9 obvious.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) over Makino *et al.* in view of Watanabe *et al.*

IV. Acknowledgement of the Allowable Claims

Applicants hereby continue to gratefully acknowledge the Examiner's previous indication of the allowability of claims 10 and 11.

V. Conclusion

Reconsideration and allowance of the claims is requested in light of the arguments provided above. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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